Docket No. CDS-0237

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Jian Zheng

Serial No. : 09/823,077 Art Unit: 1648

Filed : March 30, 2001 Examiner: Shanon A. Foley

For : NOVEL HEPATITIS B VIRUS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450 on

December 24, 2003

(Date)

Stacey B. Antar

Name of applicant, assignee, or Registered Representative

(Signature)

December 24, 2003

(Date of Signature)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Response

Dear Sir:

In response to the restriction requirement mailed on September 2, 2003, please enter the following response. A three-month extension of time and authorization to charge the appropriate fee to our deposit account are also enclosed.

In a restriction requirement dated September 2, 2003, the Examiner required restriction under 35 U.S.C. § 121 between the claims of the following groups:

Group I: claim 1, directed to an isolated hepatitis B surface antigen variant, Class 530, subclass 350;

Group II: claim 2, directed to an expression vector, class 435, subclass 320.1;

Group III: claim 3, directed to a monoclonal antibody, class 530, subclass 388.3;

Group IV: claim 4, directed to a hybridoma, class 935, subclass 89; and

Group V: claims 5 and 6, directed to kit and method to determine the presence of the antigen, class 435, subclass 7.1.

Applicants provisionally elect to prosecute Group I, with traverse. Applicants traverse the restriction requirement as improper because it is not in accord with the guidelines set forth in detail in the Manual of Patent Examining Procedure (M.P.E.P.). Specifically, M.P.E.P. § 803 provides:

> If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions. (Emphasis added).

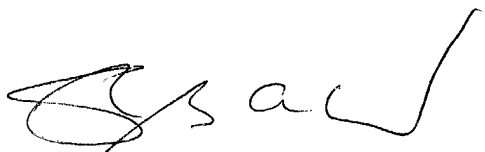
Thus, for a restriction requirement to be proper, the Examiner must establish two criteria: (1) the existence of independent and distinct inventions (35 U.S.C. § 121); and (2) that the search and examination of the entire application cannot be made without serious burden. See M.P.E.P. § 803.

The Examiner has not met the second requirement with respect to Groups I-V. Once the variant hepatitis B surface antigen, as claimed in claim 1, has been searched, the search for an expression vector for the variant, a monoclonal antibody raised against the variant, a hybridoma which secretes said antibody, and an assay kit and method utilizing said antibody cannot be a truly "serious burden."

For these reasons, Applicants respectfully requests the Examiner reconsider examining the entire application.

If any other fees are due in connection with the filing of the subject Amendment, authorization is hereby given to charge the amount of such fee to Deposit Account No. 10-0750/CDS-0237/SBA in the name of Johnson & Johnson.

Respectfully submitted,



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